HOUSE No. 2702

By Mr. Scibak of South Hadley, petition of John W. Scibak and others relative to establishing a drug repository program in the commonwealth. Public Health.

The Commonwealth of Massachusetts

PETITION OF:

John W. Scibak
David B. Sullivan
Colleen M. Garry
Mary E. Grant
David Paul Linsky
Mary S. Rogeness
Shirley Gomes

Michael E. Festa
Barbara A. L'Italien
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Thomas J. O'Brien

In the Year Two Thousand and Five.

AN ACT TO ESTABLISH A DRUG REPOSITORY PROGRAM.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

- 1 SECTION 1. Notwithstanding any general or special law to the
- 2 contrary, the Department of Public Health and the Board of Regis-
- 3 tration in Pharmacy shall establish a drug repository program to
- 4 accept and dispense prescription drugs donated for the purpose of
- 5 being dispensed to individuals who are residents of the Common-
- 6 wealth and meet the eligibility standards established in the admin-
- 7 istrative regulations promulgated by the Department and the
- 8 Board pursuant to Section 5 of this Act.
- 1 SECTION 2. Only drugs in their original sealed and tamper-
- 2 evident unit dose packaging may be accepted and dispensed. The
- 3 packaging must be unopened, except that drugs packaged in single
- 4 unit doses may be accepted and dispensed when the outside pack-
- 5 aging is opened if the single unit dose packaging is undisturbed.

- 6 Drugs donated by individuals bearing an expiration date that is
- 7 less than six months from the date the drug is donated shall not be
- accepted or dispensed. A drug shall not be accepted or dispensed
- 9 if there is reason to believe that it is adulterated pursuant to
- 10 section 186 of chapter 94 of the General Laws. Nothing in this
- section shall be construed as prohibiting a pharmacy from
- 12 accepting drugs that are not eligible to be dispensed under the
- 13 drug repository program for the proper disposal of those drugs.
- 1 SECTION 3. (a) Any person, including a drug manufacturer, health care facility, or government entity, may donate prescription drugs to the drug repository program. The drugs must be donated at a pharmacy, hospital, or a nonprofit clinic that elects to participate in the drug repository program and meets the criteria for participation established by rule of the Department. Participation in the program by pharmacies, hospitals and nonprofit clinics shall
- be voluntary. Nothing in this Act shall require a pharmacy, hospital or nonprofit clinic to participate in the program.
- (b) A pharmacy, hospital, or nonprofit clinic that participates in 10 the program shall dispense drugs to individuals who meet the eligibility standards established, or to other government entities and nonprofit private entities to be dispensed to individuals who meet the eligibility standards. A drug may be dispensed only pursuant
- to a valid drug order. A pharmacy, hospital or nonprofit clinic
- 16 that accepts donated drugs shall comply with all applicable federal
- laws and laws of the Commonwealth dealing with storage and dis-17
- tribution of dangerous drugs and shall inspect all drugs before dis-
- pensing them to determine that they are not adulterated. The
- pharmacy, hospital, or nonprofit clinic may charge individuals
- 21 receiving donated drugs a handling fee established in accordance with the administrative regulations promulgated by the Depart-
- ment and the Board under Section 5 of this Act.
- (c) Drugs donated to the repository shall not be resold. 24
- 1 SECTION 4. (a) The Department of Public Health; the Board
- 2 of Registration in Pharmacy, any person, including a drug manu-
- 3 facturer, health care facility, or government entity that donates
- 4 drugs to the repository program; any pharmacy, hospital, nonprofit
- 5 clinic or health care professional that accepts or dispenses drugs

- 6 under the program; and any pharmacy, hospital, or nonprofit clinic
- 7 that employs a health care professional who accepts or dispenses
- 8 drugs under the program shall not, in the absence of bad faith, be
- 9 subject to any criminal prosecution, liability in tort or other civil
- 10 action for injury, death, or loss to person or property; or profes-
- 11 sional disciplinary action, relating to donating, accepting, or dis-
- 12 pensing drugs under the drug repository program.
- 13 (b) A drug manufacturer shall not, in the absence of bad faith,
- 4 be subject to criminal prosecution or liability in tort or other civil
- 15 action for injury, death, or loss to person or property for matters
- 16 related to the donation, acceptance, or dispensing of a drug manu-
- 17 factured by the drug manufacturer that is donated under the pro-
- 18 gram, including but not limited to liability for failure to transfer or
- 19 communicate product or consumer information or the expiration
- 20 date of the donated drug.
- 1 SECTION 5. In consultation with the Department of Public
- 2 Health, the Board of Registration in Pharmacy shall establish rules
- 3 and regulations governing the drug repository program that estab-
- 4 lish all of the following:
- 5 (a) Eligibility criteria for pharmacies, hospitals, and nonprofit
- 6 clinics to receive and dispense donated drugs under the program;
- (b) Standards and procedures for accepting, safely storing, and dispensing donated drugs;
- 9 (c) Standards and procedures for inspecting donated drugs to
- 10 determine that the original unit dose packaging is sealed and 11 tamper-evident and that the drugs are unadulterated, safe and suit-
- 12 able for dispensing;
- 13 (d) Eligibility standards based on economic need for individ-
- 14 uals to receive drugs;
- 15 (e) A means, such as an identification card, by which an indi-
- 16 vidual who is eligible to receive donated drugs may demonstrate
- 17 eligibility to the pharmacy, hospital, or nonprofit clinic dispensing
- 18 the drugs;
- 19 (f) A form that an individual receiving a drug from the reposi-
- 20 tory must sign before receiving the drug to confirm that the indi-
- 21 vidual understands the immunity provisions of the program;

- 22 (g) A formula to determine the handling fee that pharmacies, 23 hospitals, and nonprofit clinics may charge to drug recipients to
- 24 cover restocking and dispensing costs;
 - (h) For drugs donated to the repository by individuals:
- 1. A list of drugs, arranged either by category or by individual drug, that the repository will accept from individuals;
- 28 2. A list of drugs, arranged either by category or by individual 29 drug, that the repository will not accept from individuals, 30 including a statement as to why the drug is ineligible for donation; 31 and
- 32 3. A form each donor must sign stating that the donor is the 33 owner of the drugs and intends to voluntarily donate them to the 34 repository;
- 35 (i) For drugs donated to the repository by health care facilities 36 or governmental entities:
- 1. A list of drugs, arranged either by category or by individual drug, that the repository will accept from health care facilities or governmental entities;
- 40 2. A list of drugs, arranged either by category or by individual 41 drug, that the repository will not accept from health care facilities 42 or governmental entities, including a statement as to why the drug 43 is ineligible for donation; and
- 44 (j) Any other standards and procedures the Board considers 45 appropriate.